



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 050972 0053 Rev. 01

Holder of Certificate: **Contec Medical Systems Co., Ltd.**

No.112 Qinhuang West Street
Economic& Technical Development Zone
066004 Qinhuangdao, Hebei Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production, Sales and Servicing of Dynamic EEG Systems, Dynamic ECG Systems, Digital Brain Electric Activity Mapping, Patient Monitor, Patient Monitor System, B-Ultrasound Diagnostic System, Electrocardiograph, ECG Workstation, Fetal Monitor, Ventilator, Pulse Oximeter, Pocket Fetal Doppler, Maternal/Fetal Monitor, Infusion Pump, Spirometer, Ambulatory Blood Pressure Monitor, Electronic Sphygmomanometer, EMG/EP System, Pulse Oximeter Probe, ECG Electrode Cable And Accessories, NIBP Cuff, Portable ECG Monitor, Semi-auto Biochemistry Analyzer, Urine Analyzer, Oxygen concentrator, Multi-parameter Vital Signs Monitor, Sleep apnea screen meter, Arteriosclerosis Detector, Compressor Nebulizer, Wearable Monitor, Electronic Thermometer, Mesh Nebulizer, Capnograph, Infrared Thermometer, Portable Phlegm Suction Unit, Positive Airway Pressure Devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q-cert:Q5 050972 0053 Rev. 01

Report No.: BJ24090201

Valid from: 2025-03-02

Valid until: 2028-03-01

Christoph Dicks

Head of Certification/Notified Body

Date, 2025-02-18



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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

Contec Medical Systems Co., Ltd.

No.112 Qinhuang West Street, Economic& Technical
Development Zone, 066004 Qinhuangdao, Hebei Province,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate